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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,353	07/05/2005	Christine Bain	124238	3250
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OLIFF & BERRIDGE, PLC P.O. BOX 19928 ALEXANDRIA, VA 22320			EXAMINER BOESEN, AGNIESZKA	
			ART UNIT 1648	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,353	Applicant(s) BAIN ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 10, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21-23 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19, 21-23 and 25-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's preliminary amendments filed July 5, 2005 and March 10, 2006 are acknowledged. Claims 1-19, 21-23, and 25-32 are pending and are subject to the following restriction.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Claim 1 link(s) inventions I, II, III, and IV. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claim 1. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such

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claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group I, claims 2, 21, and 22, drawn to a polypeptide characterized in that it has SEQ ID NO: 1.

Group II, claim 3 drawn to a polypeptide characterized in that it has SEQ ID NO: 2.

It is noted Applicant's preferred embodiment, as recited in claim 3 is SEQ ID NO: 2.

However if Applicant wishes to choose another preferred embodiment other than SEQ ID NO: 2, further restriction is required to **elect one sequence** from SEQ ID NO: 3 to SEQ ID NO: 150. The elected sequence will replace SEQ ID NO: 2 in group II.

Group III, claim 4 drawn to a polypeptide characterized in that it has SEQ ID NO: 151

Group IV, claim 5, drawn to a polypeptide characterized in that it has SEQ ID NO: 152.

It is noted Applicant's preferred embodiment, as recited in claim 5 is SEQ ID NO: 152.

However if Applicant wishes to choose another preferred embodiment other than SEQ ID NO: 152, further restriction is required to **elect one sequence** from SEQ ID NO: 153 to SEQ ID NO: 176. The elected sequence will replace SEQ ID NO: 152 in group IV.

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Group V, claims 6, 15-18, and 25 drawn to a nucleotide sequence encoding a polypeptide that induces an immune response against HCV, characterized in that it consists of 99 amino acids located between positions 43 and 141 of HCV polypeptide.

Group VI, claims 7 and 8, drawn to an epitope characterized in that it has SEQ ID NO: 177.

It is noted Applicant's preferred embodiment, as recited in claim 8 is SEQ ID NO: 177. However if Applicant wishes to choose another preferred embodiment other than SEQ ID NO: 177, further restriction is required to **elect one sequence** from SEQ ID NO: 178 to SEQ ID NO: 235. The elected sequence will replace SEQ ID NO: 177 in group VI.

Group VII, claims 9 and 10, drawn to an epitope characterized in that it has SEQ ID NO: 236.

It is noted Applicant's preferred embodiment, as recited in claim 10 is SEQ ID NO: 236. However if Applicant wishes to choose another preferred embodiment other than SEQ ID NO: 236, further restriction is required to **elect one sequence** from SEQ ID NO: 237 to SEQ ID NO: 283. The elected sequence will replace SEQ ID NO: 236 in group VII.

Group VIII, claims 11 and 12, drawn to an epitope characterized in that it has SEQ ID NO: 284.

It is noted Applicant's preferred embodiment, as recited in claim 12 is SEQ ID NO: 284. However if Applicant wishes to choose another preferred embodiment other than SEQ ID

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NO: 284, further restriction is required to **elect one sequence** from SEQ ID NO: 285 to SEQ ID NO: 358. The elected sequence will replace SEQ ID NO: 284 in group VIII.

Group IX, claims 13 and 14, drawn to an epitope characterized in that it has SEQ ID NO: 359.

It is noted Applicant's preferred embodiment, as recited in claim 14 is SEQ ID NO: 359. However if Applicant wishes to choose another preferred embodiment other than SEQ ID NO: 359, further restriction is required to **elect one sequence** from SEQ ID NO: 360 to SEQ ID NO: 434. The elected sequence will replace SEQ ID NO: 359 in group IX.

Group X, claims 19, drawn to an antibody directed against HCV protein characterized in that it consists of 99 amino acids located between positions 43 and 141 of HCV polyprotein.

Group X, claims 19, drawn to an antibody directed against HCV protein characterized in that it consists of 99 amino acids located between positions 43 and 141 of HCV polyprotein.

Group XI, claim 26, drawn to an antibody against the epitope as defined in claim 7.

Group XII, claim 27, drawn to an antibody against the epitope as defined in claim 9.

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Group XIII, claim 28, drawn to an antibody against the epitope as defined in claim 11.

Group XIV, claim 29, drawn to an antibody against the epitope as defined in claim 13.

Group XV, claim 30, drawn to a nucleotide sequence encoding the epitope as defined in claim 9.

Group XVI, claim 31, drawn to a nucleotide sequence encoding the epitope as defined in claim 11.

Group XVII, claim 30, drawn to a nucleotide sequence encoding the epitope as defined in claim 13.

Group XVIII, claim 23, drawn to a method for detecting and/or quantifying the HCV in a biological sample.

The inventions listed in groups I - XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features for the following reasons: the special technical feature of the claimed invention is a polypeptide and an epitope that induce an immune response against the HCV, and an antibody against the polypeptide of HCV polyprotein. Leroux-Roels et al. (US Patent 6,689,368 B1) discloses a polypeptide and an epitope that induce an immune response against the HCV, and an

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antibody against the polypeptide of HCV polyprotein (see the entire document, particularly claims 1-66).

Since Applicant's invention does not contribute a special technical feature when viewed over the prior art they do not have a single inventive concept and thus the claims lack unity of invention. Therefore, the instant invention lacks Unity of Invention and restriction is set forth as it applies to U.S. practice.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday – Friday 9:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AB

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 7-30-2007
Primary Examiner, TC1600